K002067

JAN 1 1 2001

3 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's Information:

Name:	RADI Medical Systems AB
Address:	Palmbladsgatan 10, SE-754 50 Uppsala, Sweden
Phone/Fax:	+46-18-161000 / +46-18-161099
Contact Person:	Mats Granlund
Date of Preparation:	July 4, 2000

Device Name:

Trade Names: RadiAnalyzer™
Common Name: Blood Pressure Computer
Classification Name: §870.1110 Blood pressure computer

Predicate Device Names: PressureWire Interface (K972793)
WaveMap Pressure Instrument (K965140)

Device Description:

The RadiAnalyzer™ is a blood pressure computer, to be used as a diagnostic tool when the diagnosis is based on patient blood pressures.
The device comprises a graphic display that presents real-time pressure curves as well as numerical values, and is operated via a remote control.
The device has two entries for pressure signals, one for a PressureWire™ Sensor, and another for an External Pressure Transducer (EPT) and corresponding outlets for connection to a cardiac monitor.

Intended Use:

The RadiAnalyzer is intended for use under the direction of a licensed physician to calculate, display and record vascular data. Data is acquired from a PressureWire Sensor and an External Pressure Transducer (EPT).
The information is displayed on the integrated screen and/or transferred to a cardiac monitor. Data includes: systolic, diastolic and mean blood pressure, heart rate, and Fractional Flow Reserve (FFR).
The RadiAnalyzer is intended for use in catheterization and related cardiovascular specially laboratories.

Technical Characteristic:

The mechanical, electrical and signal properties of RadiAnalyzer™ are similar to the predicate devices. Unlike the predicate devices which have the control buttons directly on their main unit, the RadiAnalyzer™ has a remote control to facilitate the usage of the device.

Performance Data:

The RadiAnalyzer™ complies with the voluntary standards as detailed in section 7 of this submission. The following quality assurance measures were applied to the development of the RadiAnalyzer™.

- Requirements specification review
- Code inspection
- Software and hardware testing
- Safety testing
- Environmental testing
- Final validation

Conclusions:

The results of these measures demonstrates that the RadiAnalyzer™ System is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2001

Mr. Mats Granlund
Quality & Regulatory Affairs Manager
RADI Medical Systems AB
Palmbladsgatan 10
SE-754 50 Uppsala, Sweden

Re: K002067
Trade Name: RadiAnalyzer™ System
Regulatory Class: II (two)
Product Code: 74 DSK
Dated: October 25, 2000
Received: October 27, 2000

Dear Mr. Granlund:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2 Statement of Indications for Use

510(k) Number: K 002067

Device Name: RadiAnalyzer™ System

Indications for Use: The RadiAnalyzer is intended for use under the direction of a licensed physician to calculate, display and record vascular data. Data is acquired from a PressureWire Sensor and an External Pressure Transducer (EPT).
The information is displayed on the integrated screen and/or transferred to a cardiac monitor. Data includes: systolic, diastolic and mean blood pressure, heart rate, and Fractional Flow Reserve (FFR).
The RadiAnalyzer is intended for use in catheterization and related cardiovascular specially laboratories.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

1-10-1

Division of Cardiovascular & Respiratory Devices
510(k) Number K002067

(Optional Format 1/2/96)